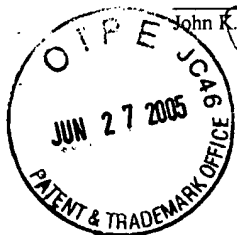
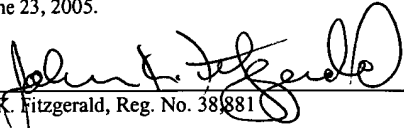


CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

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COFC
Certificate
JUN 30 2005
of Correction




John K. Fitzgerald, Reg. No. 38881

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of

TIMOTHY R. MACHOLD ET AL.

Patent No.: 6,890,347 B2

Issued: May 10, 2005

Serial No: 10/628,055

Filed: July 25, 2003

For: DISPOSABLE CASSETTE FOR
INTRAVASCULAR HEAT
EXCHANGE CATHETER

Examiner: Robert L. Nasser

Group Art Unit: 3736

Client ID/Matter No: RADME 64499

REQUEST FOR CERTIFICATE OF CORRECTION

Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The above-identified patent has been found to have the errors set forth in the enclosed Certificate of Correction. It is requested that this Certificate of Correction be issued and returned to us. Since these errors occurred in both the final printing phase of the patent and in the final application, a check in the amount of \$100.00 is enclosed to

06/28/2005 HVJONG1 00000028 6890347

01 FC:1811

100.00 DP

JUL - 5 2005

cover the necessary fees. Should the Office determine that additional fees are needed, please charge Deposit Account No. 06-2425.

The errors are verifiable in the patent application file as follows:

ERROR

VERIFICATION

| | |
|--|---|
| Column 1, line 26, delete "99.6" and insert --98.6--. | Patent Application filed on July 25, 2003. See Attachment A, page 1. |
| Column 4, line 64, delete "printing" and insert --priming--. | Patent Application filed on July 25, 2003. See Attachment A, page 6. |
| Column 5, line 57, delete "though" and insert --through--. | Applicant error. |
| Column 11, line 27, delete "illustrates" and insert --illustrated--. | Applicant error. |
| Column 11, line 39, delete "has an" and insert --having an--. | Applicant error. |
| Column 14, line 16, delete "lain" and insert --laid--. | Applicant error. |
| Column 18, line 20, delete "even" and insert --event--. | Applicant error. |
| Column 18, line 55, delete "generates" and insert --generate--. | Applicant error. |
| Column 24, line 39, delete "further comprises" and insert --be further comprised of--. | Applicant error. |
| Column 30, line 46, delete "seal" and insert --seals--. | Applicant error. |

These errors occurred in good faith and correction thereof does not involve such changes in the patent as would constitute new matter or would require re-examination. It is requested that a Certificate of Correction be issued and returned to us.

Attached hereto, in duplicate, is Form PTO-1050, with at least one copy being suitable for printing.

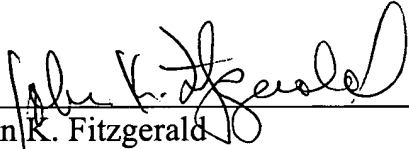
A duplicate of this document is attached.

Date: June 23, 2005

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: _____


John K. Fitzgerald
Registration No. 38,881

JKF:ck
Enclosures

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201

93629.1

JUL - 5 2005

DISPOSABLE CASSETTE FOR INTRAVASCULAR HEAT EXCHANGE CATHETERIntroductionCross Reference To Related Applications

5 This application is a Continuation-In-Part of U.S. Patent Application Serial No. 09/138,830, filed on August 24, 1998; and claims the benefit of US Provisional Application No. 60/185,561, filed on February 28, 2000.

Technical Field

10 The present invention is directed to a fluid supply and fluid handling mechanism for an intravascular heat exchanger, and more particularly to a disposable cassette with a pump head and an external heat exchanger for use as a system to provide hot or cold heat transfer fluid to an intravascular heat exchange catheter.

Background

15 Under ordinary circumstances, thermoregulatory mechanisms exist in the healthy human body to maintain the body at a constant temperature of about 37°C (98.6°F), a condition sometimes referred to as normothermia. To maintain normothermia, the thermoregulatory mechanisms act so that heat lost to the environment is replaced by the same amount of heat generated by metabolic activity in the body.

20 For various reasons, however, a person may accidentally develop a body temperature that is above or below normal, conditions known as hyperthermia or hypothermia respectively. These conditions have generally been regarded as harmful and patients suffering from either condition have been treated to return them to normothermia by various mechanisms, including application of warming or cooling blankets, administration of hot or cold liquids by mouth, hot or cold liquids infused into the bloodstream, immersion of the patient in hot or cold baths, and
25 directly heating or cooling blood during cardiopulmonary bypass.

Besides treating undesirable hypothermia to reverse the condition and restore normothermia, medical science recognizes that it is sometimes valuable to intentionally induce and maintain regional or whole body hypothermia for therapeutic reasons. The term "whole body hypothermia" refers to the condition where the whole body temperature, usually measured
30 as the core body temperature, is below normothermia. "Regional hypothermia" refers to the condition where target tissue of one region of the body such as the brain or the heart is maintained at a temperature below normothermia. During regional hypothermia, the core body

Another aspect of the invention is a disposable cassette for supplying a heat exchange fluid to an intravascular heat exchange catheter, the cassette having a bulkhead and an external heat exchanger. The external heat exchanger has a thin heat exchanger layer and a back plate fused together to form a serpentine flow channel or a plurality of flow channels, and has an inlet orifice and an outlet orifice that allow fluid to circulate through the external heat exchanger and which communicate with the bulkhead. In one embodiment, the bulkhead has three components which can be independent sections coupled together or where at least two of the sections are housed together: a reservoir section, a feedblock section and a pump section. The reservoir section has an inlet hole leading from the external heat exchanger and an outlet leading to the feedblock section, a fluid reservoir for storage of heat exchange fluid, a fluid level detector for monitoring the level of heat exchange fluid within the fluid reservoir, a cover plate that functions to retain fluid within the reservoir and which is fitted with at least one vent hole into which is positioned a hydrophobic vent for releasing air contained within the fluid reservoir. The feedblock section has a central chamber which houses a priming valve that directs fluid flow, an inlet and corresponding inlet channel from the reservoir and an inlet and corresponding inlet channel from an external fluid source which both lead into the central chamber, an outflow channel leading from the central chamber to an outlet which is directed to the pump head, a flexible membrane covering the central chamber, a flow-through channel having an inlet which leads from the pump head and a fluid coupling outlet means for fluidly connecting the catheter to the bulkhead, and a flow-through channel having a fluid coupling inlet means for fluidly connecting the catheter to the bulkhead and an outlet which leads to the pump section and then to the external heat exchanger. The pump section has a quasi-cardioid shaped cavity, into which is positioned a rotor is fitted with a vane for moving fluid from an inlet and inlet channel to an outlet channel and outlet, a wheel assembly to facilitate movement of the rotor and a flow-through channel having an inlet that leads from the feedblock section and an outlet which leads to the external heat exchanger.

In yet another aspect of the invention, the bulkhead has two components: a reservoir section and a pump section, where the pump and reservoir sections are configured similar to that described above, except that the outlet of the reservoir section leads to the pump section and the reservoir further comprises a pressure damper and an inlet in fluid communication with an external fluid source.

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO. : 6,890,347 B2

DATED : May 10, 2005

INVENTOR(S) : Timothy R. Machold et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1,

Line 26, delete "99.6" and insert --98.6--.

Column 4,

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Column 24,

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Column 30,

Line 46, delete "seal" and insert --seals--.

MAILING ADDRESS OF SENDER:

**John K. Fitzgerald
Fulwider Patton Lee & Utecht LLP
6060 Center Drive, 10th Floor
Los Angeles, CA 90045**

PATENT NO. 6,890,347 B2

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Page 1 of 1

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PTO/SB/21 (09-04)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Total Number of Pages in This Submission

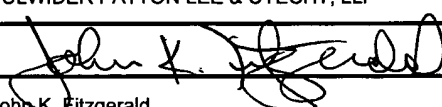
| | |
|------------------------|------------------|
| Application Number | 10/628,055 |
| Filing Date | 7/25/03 |
| First Named Inventor | Machold et al. |
| Art Unit | 3736 |
| Examiner Name | Robert L. Nasser |
| Attorney Docket Number | RADME-64499 |

ENCLOSURES (Check all that apply)

- | | | |
|--|--|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Request for Certificate of Correction (+Exhibit A), Certificate of Correction, Postcard |
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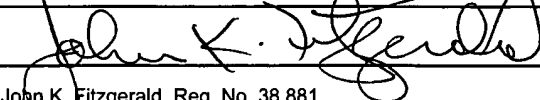
Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|--------------|---|----------|--------|
| Firm Name | FULWIDER PATTON LEE & UTECHT, LLP | | |
| Signature |  | | |
| Printed name | John K. Fitzgerald | | |
| Date | 6/23/05 | Reg. No. | 38,881 |

CERTIFICATE OF TRANSMISSION/MAILING

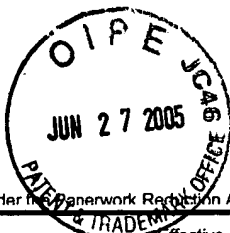
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| Signature |  | | |
| Typed or printed name | John K. Fitzgerald, Reg. No. 38,881 | Date | 6/23/05 |

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PTO/SB/17 (12-04v2)

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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).**FEE TRANSMITTAL**
For FY 2005☒ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 100.00**Complete if Known**

| | |
|----------------------|------------------|
| Application Number | 10/628,055 |
| Filing Date | 7/25/03 |
| First Named Inventor | Machold et al. |
| Examiner Name | Robert L. Nasser |
| Art Unit | 3736 |
| Attorney Docket No. | RADME-64499 |

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____☒ Deposit Account Deposit Account Number: 06-2425 Deposit Account Name: FULWIDER PATTON

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| Application Type | FILING FEES | | SEARCH FEES | | EXAMINATION FEES | | Fees Paid (\$) |
|------------------|-------------|-----------------------|-------------|-----------------------|------------------|-----------------------|----------------|
| | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | |
| Utility | 300 | 150 | 500 | 250 | 200 | 100 | |
| Design | 200 | 100 | 100 | 50 | 130 | 65 | |
| Plant | 200 | 100 | 300 | 150 | 160 | 80 | |
| Reissue | 300 | 150 | 500 | 250 | 600 | 300 | |
| Provisional | 200 | 100 | 0 | 0 | 0 | 0 | 0 |

2. EXCESS CLAIM FEES**Fee Description**

| | Fee (\$) | Small Entity Fee (\$) |
|--|----------|-----------------------|
| Each claim over 20 (including Reissues) | 50 | 25 |
| Each independent claim over 3 (including Reissues) | 200 | 100 |
| Multiple dependent claims | 360 | 180 |

| | | | |
|---------------------|---------------------|-----------------|----------------------|
| Total Claims | Extra Claims | Fee (\$) | Fee Paid (\$) |
| - 20 or HP = | x | = | 0 |

HP = highest number of total claims paid for, if greater than 20.

| | | | |
|----------------------|---------------------|-----------------|----------------------|
| Indep. Claims | Extra Claims | Fee (\$) | Fee Paid (\$) |
| - 3 or HP = | x | = | 0 |

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| | | | | |
|---------------------|---------------------|---|-----------------|----------------------|
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof | Fee (\$) | Fee Paid (\$) |
| - 100 = | / 50 = | (round up to a whole number) x | = | 0 |

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Request for Certificate of Correction**Fees Paid (\$)**

\$100.00

SUBMITTED BY

Signature

Registration No. 38,881
(Attorney/Agent)

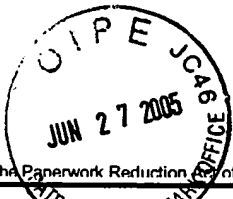
Telephone 310/824-5555

Name (Print/Type) John K. Fitzgerald

Date 6/23/05

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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL

For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

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Complete if Known

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| Application Number | 10/628,055 |
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| First Named Inventor | Machold et al. |
| Examiner Name | Robert L. Nasser |
| Art Unit | 3736 |
| Attorney Docket No. | RADME-64499 |

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 06-2425 Deposit Account Name: FULWIDER PATTON

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☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

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FEE CALCULATION

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| Reissue | 300 | 150 | 500 | 250 | 600 | 300 | |
| Provisional | 200 | 100 | 0 | 0 | 0 | 0 | 0 |

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HP = highest number of total claims paid for, if greater than 20.

Indep. Claims - 3 or HP = _____ x _____ = _____
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Extra Sheets Number of each additional 50 or fraction thereof Fee (\$)

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Other (e.g., late filing surcharge): Request for Certificate of Correction

Fees Paid (\$)
\$100.00

SUBMITTED BY

| | | | |
|-------------------|--------------------|--|------------------------|
| Signature | | Registration No. 38,881 (Attorney/Agent) | Telephone 310/824-5555 |
| Name (Print/Type) | John K. Fitzgerald | | Date 6/23/05 |

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John K. Fitzgerald
John K. Fitzgerald, Reg. No. 38881

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of

TIMOTHY R. MACHOLD ET AL.

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Serial No: 10/628,055

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Examiner: Robert L. Nasser

Group Art Unit: 3736

Client ID/Matter No: RADME 64499

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| Column 1, line 26, delete "99.6" and insert --98.6--. | Patent Application filed on July 25, 2003. See Attachment A, page 1. |
| Column 4, line 64, delete "printing" and insert --priming--. | Patent Application filed on July 25, 2003. See Attachment A, page 6. |
| Column 5, line 57, delete "though" and insert --through--. | Applicant error. |
| Column 11, line 27, delete "illustrates" and insert --illustrated--. | Applicant error. |
| Column 11, line 39, delete "has an" and insert --having an--. | Applicant error. |
| Column 14, line 16, delete "lain" and insert --laid--. | Applicant error. |
| Column 18, line 20, delete "even" and insert --event--. | Applicant error. |
| Column 18, line 55, delete "generates" and insert --generate--. | Applicant error. |
| Column 24, line 39, delete "further comprises" and insert --be further comprised of--. | Applicant error. |
| Column 30, line 46, delete "seal" and insert --seals--. | Applicant error. |

These errors occurred in good faith and correction thereof does not involve such changes in the patent as would constitute new matter or would require re-examination. It is requested that a Certificate of Correction be issued and returned to us.

Attached hereto, in duplicate, is Form PTO-1050, with at least one copy being suitable for printing.

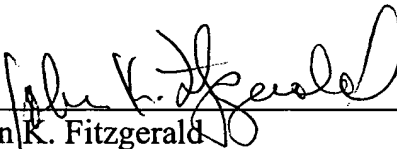
A duplicate of this document is attached.

Date: June 23, 2005

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By:



John K. Fitzgerald
Registration No. 38,881

JKF:ck
Enclosures

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201

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DISPOSABLE CASSETTE FOR INTRAVASCULAR HEAT EXCHANGE CATHETERIntroductionCross Reference To Related Applications

5 This application is a Continuation-In-Part of U.S. Patent Application Serial No. 09/138,830, filed on August 24, 1998; and claims the benefit of US Provisional Application No. 60/185,561, filed on February 28, 2000.

Technical Field

10 The present invention is directed to a fluid supply and fluid handling mechanism for an intravascular heat exchanger, and more particularly to a disposable cassette with a pump head and an external heat exchanger for use as a system to provide hot or cold heat transfer fluid to an intravascular heat exchange catheter.

Background

15 Under ordinary circumstances, thermoregulatory mechanisms exist in the healthy human body to maintain the body at a constant temperature of about 37°C (98.6°F), a condition sometimes referred to as normothermia. To maintain normothermia, the thermoregulatory mechanisms act so that heat lost to the environment is replaced by the same amount of heat generated by metabolic activity in the body.

20 For various reasons, however, a person may accidentally develop a body temperature that is above or below normal, conditions known as hyperthermia or hypothermia respectively. These conditions have generally been regarded as harmful and patients suffering from either condition have been treated to return them to normothermia by various mechanisms, including application of warming or cooling blankets, administration of hot or cold liquids by mouth, hot or cold liquids infused into the bloodstream, immersion of the patient in hot or cold baths, and
25 directly heating or cooling blood during cardiopulmonary bypass.

Besides treating undesirable hypothermia to reverse the condition and restore normothermia, medical science recognizes that it is sometimes valuable to intentionally induce and maintain regional or whole body hypothermia for therapeutic reasons. The term "whole body hypothermia" refers to the condition where the whole body temperature, usually measured
30 as the core body temperature, is below normothermia. "Regional hypothermia" refers to the condition where target tissue of one region of the body such as the brain or the heart is maintained at a temperature below normothermia. During regional hypothermia, the core body

Another aspect of the invention is a disposable cassette for supplying a heat exchange fluid to an intravascular heat exchange catheter, the cassette having a bulkhead and an external heat exchanger. The external heat exchanger has a thin heat exchanger layer and a back plate fused together to form a serpentine flow channel or a plurality of flow channels, and has an inlet orifice and an outlet orifice that allow fluid to circulate through the external heat exchanger and which communicate with the bulkhead. In one embodiment, the bulkhead has three components which can be independent sections coupled together or where at least two of the sections are housed together: a reservoir section, a feedblock section and a pump section. The reservoir section has an inlet hole leading from the external heat exchanger and an outlet leading to the feedblock section, a fluid reservoir for storage of heat exchange fluid, a fluid level detector for monitoring the level of heat exchange fluid within the fluid reservoir, a cover plate that functions to retain fluid within the reservoir and which is fitted with at least one vent hole into which is positioned a hydrophobic vent for releasing air contained within the fluid reservoir. The feedblock section has a central chamber which houses a priming valve that directs fluid flow, an inlet and corresponding inlet channel from the reservoir and an inlet and corresponding inlet channel from an external fluid source which both lead into the central chamber, an outflow channel leading from the central chamber to an outlet which is directed to the pump head, a flexible membrane covering the central chamber, a flow-through channel having an inlet which leads from the pump head and a fluid coupling outlet means for fluidly connecting the catheter to the bulkhead, and a flow-through channel having a fluid coupling inlet means for fluidly connecting the catheter to the bulkhead and an outlet which leads to the pump section and then to the external heat exchanger. The pump section has a quasi-cardioid shaped cavity, into which is positioned a rotor is fitted with a vane for moving fluid from an inlet and inlet channel to an outlet channel and outlet, a wheel assembly to facilitate movement of the rotor and a flow-through channel having an inlet that leads from the feedblock section and an outlet which leads to the external heat exchanger.

In yet another aspect of the invention, the bulkhead has two components: a reservoir section and a pump section, where the pump and reservoir sections are configured similar to that described above, except that the outlet of the reservoir section leads to the pump section and the reservoir further comprises a pressure damper and an inlet in fluid communication with an external fluid source.